

# SPL ER/DL Team

## May 23, 2012

### Minutes

**Chair: Pat Cowall**

Teleconference information:

USA Toll-Free 866-213-2145

Access code: 273 8216

#### Topics

##### 1. New Section header: Health Care Provider Letter Section (drug shortages)

- Companies have been offering for import drugs associated with US drugs in a shortage situation.
- If you have a drug in this situation, then FDA will already have contacted you with this information. FDA has worked with some of these companies already to work out details, and will be issuing a Validation rule e-mail when this type of SPL file is going live.
- Internal discussions: drug products offered for import as part of the drug shortage remediation should be listed.
  - These products are only to be imported on a temporary basis.
  - There can also be reimbursement issues – so FDA needed to add new terminology to address the situation of drugs import
- New marketing category: Unapproved drug for use in drug shortage
- Data and Validation rules:
  - Validation rule will require the Dear HCP text in the first section.
  - At this time, these establishments do not need to be registered. There will be a requirement that there be establishment information, just not a check against already registered establishments
  - Labeler code request file will probably be required.
  - Dear Healthcare Provider letter needs to be included in the file as the first section of the SPL.
  - Market end date = likely to be the expiry date of the last lot.
  - What about foreign language in the label? CBER, CDER and CVM have all been having discussions on how to handle the listings for this product.
- Gateway accounts:
  - Companies needing to list that didn't previously have Gateway accounts – the ESG group has agreed to expedite the establishment of accounts.
- Drug Shortages site for more general information:
  - <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>
  - <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm> - links to Dear Customer letters are throughout the table of current Drug Shortages.

Notes: Kathy Lins (hospira) has a product on Daily Med. Easier than they expected. She just had to copy the trade SPL into a new SPL file, add the new section and marketing status, and then enter:

- Jpg
- Dear Health Care Provider letter.

## 2. Implementation of the validation procedure for the product-to-establishment data relationship for CDER-regulated drug products - July 1 , 2012

If you want to see how the SPL will look with this new information, go to the following label on the FDA Online Repository, scrolling down to the establishment data at the very end of the file: <http://www.accessdata.fda.gov/spl/data/8ee1cd0e-bad7-48ff-9e25-8710edb812ec/8ee1cd0e-bad7-48ff-9e25-8710edb812ec.xml>.

The label is also available on the DailyMed but the stylesheet on that site does not appropriately display the information. (<http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?ndc=63459-548-28&start=1&labeltype=all>)

Discussion:

CVM isn't implementing this rule.

CBER doesn't want it but will accept SPL with this data.

## 3. "SPL Downloadable Data" and Inner Packs:

Discussion:

Information about inner packs are now available in 2 places.

- Inner NDCs now displayed in description field of NDC directory:
- Download available on SPL Resources page.

## 3. Including inner NDC codes in SPL Data for CBER products-- when both the inner and outer packaging contain the same NDC code (eg vial in an outer carton):

Continued discussion from March 28 teleconference:

**Beverly Haslip:** We recently received a SPL validation error from **CBER** for a **One-count carton finished pack** where originally the carton and inner syringe NDC were the same. CBER requested/required that a different NDC be used for each level of packaging. Historically for this type of packaging configuration, for both CBER and CDER products, our company has used the same NDC for both the carton and the inner product.

Lonnie has previously indicated that for **CDER** products, the elist system expects different NDC's for a pack where there is multilevel packing (different types of packaging); however, at this time CDER has not implemented this validation rule. We wanted to get the groups' perspective about the application of this rule to CDER products, and see if anybody was implementing or is in the process of evaluating the use of two different NDC pack codes:.

- for a One-count finished pack e.g., one vial contained within a carton
- Multi-count carton e.g., 10 vials contained within a carton

Discussion:

CBER has new validation requirements:

- CBER: Get an error in the Pragmatic Validator --- even on 1 vial in 1 carton. Therefore needs to be a different NDC code on the vial versus the carton.
- CBER's interpretation of the bar code rule is that there needs to be a different NDC on each level of packaging.
- BAR code rule: states that each level of packaging needs a different bar code.
- Hospira: uses the same NDC code on each level of packaging. The bar code differentiates the level of packaging
- CDER
  - If CDER were to implement this rule, they would give us notice.

**5. New document type:** Establishment de-registration (Howard)

- How to remove unused site from an existing file. Submit the new file – it will override the old file.
- How to merge a company into
  - submit an “out of Business” for newly merged company
  - add the new company to the new parent company.

Discussion:

If all the establishments for a registrant are no longer making product for the US market, then -- they can use this document type to tell FDA that they have their establishments do not need to inspection.

-- If one of many establishments on a list drops off, then just resubmit the DER without the establishment. The new file supercedes the old file.

6. Mary Beth Kline: **Drug listing a foreign label** – will the FDA accept foreign labels? We need to drug list an API for one of our foreign establishments (we are their US agent) that is being exported into the US. However, their label is in German. Is this acceptable with the FDA? Has anyone else encountered this?

Discussion:

We haven't heard of any problem. However, we would advise the firm to tell their supplier to translate the label into English. This could expedite the import process.

**7. D&B update on their data portal:**

Discussion:

They have been delayed. They are expecting to have a pilot ready to show the subteam during May.

## 8. D&B data inconsistencies:

### Discussion:

When discussing how Dun & Bradstreet might have some 'inconsistent' address information with that of the actual site, Lonnie mentioned that an override can be requested if it fails at validation because of the address checking. He also noted that for overrides, the core id must be specified in the e-mail request.

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Topics to be discussed at our next meeting:

## 9. Updates from SPL Leadership Team –

- a. Usage of terms and UNII in SPL files.
  - Note: using a substance correctly.
  - Example: banana as a substance or as an artificial flavor. (This data is used by RxNorm to determine potential allergic reactions, etc)
- b. Downstream use of SPL data by FDA safety evaluators.
  - They would like to use the SPL data for their adverse event reporting.
  - Rx and OTC
  - A lot of people are very interested in the SPL data. SPL available on Daily Med and in FDA systems. Safety evaluators will send list to Lonnie.
    - Basis of strength.
  - FDA is very interested in having SPL viewed in a positive light – taking a lot of effort to create the SPL...so the data should be right.